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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/456,278	12/07/1999	Jesus Miranda	P24,540 USA	6233

7590 11/01/2004

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/456,278	MIRANDA ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 28, 30, 32, 33 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4, 5 and 8-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 7, 28, 30, 35, 37 and 38 is/are rejected.
- 7) ☒ Claim(s) 3, 32, 33 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/2/04; 9/3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and amendment, both filed 06/28/2004; IDS, filed 02/02/2004; and IDS, filed 09/03/2004.

Claims 27, 29, 31, and 43 have been canceled. Claims 1, 3, 6, 7, and 28, 30, 32, 33, 35-38 are included in the prosecution.

1. This application contains claims 2, 4, 5, and 8-26 drawn to an invention nonelected with traverse in Paper filed 10/15/2001. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3, 6, 7, 28, 30, 32, 33, and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claims recite "methacrylic acid" that is introduced new matter to the claims because nowhere in the specification applicants disclosed "methacrylic acid."

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 32, 35, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 32, 35 and 35 are indefinite because they depend on canceled claim 27.

The following rejection has been discussed in the previous office action, and is maintained in view of the new matter situation:

Claim Rejections - 35 USC § 103

6. Claims 1, 6, 7, 28, 30, 35, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,603,947 ('947) in view of US 5,914,282 ('282).

Applicants' claims 1 and 27 read as follows:

A transdermal patch comprising the following layers:

- An impermeable backing layer,
- Silicone adhesive layer containing the drug,

- Acrylic adhesive layer, and
- Removable release liner.

US '947 discloses a device for providing nicotine replacement therapy transdermally. The device comprises an impermeable backing, matrix layer containing nicotine in silicone adhesive, an adhesive layer to affix the device to the skin and a release liner (abstract; col.2, lines 16-20; col.3, lines 15-18; col.5, lines 51-53; col.6, lines 1-8, 40-45).

However, the US '947 does not teach the adhesive layer as acrylic adhesive as in component (c) of claims 1, 27, 28 and 30, or the components of the acrylic adhesive as claimed in claims 7 and 38. The reference does not teach the thickness of the adhesive layer as in claim 31.

The claimed thickness does not impart patentability to the composition claims, absent evidence to the contrary.

US '282 teaches a pressure sensitive adhesive useful for medical dressings and has the advantages of ease of manufacture, excellent safety history profile, high shear strength, low cost and chemical stability (abstract; col.1, lines 7-12; col.3, lines 48-52). The adhesive comprises a blend of two components at the ratio of 10:90 to 90:10, and the first component comprising iso octyl acrylate and ethylhexyl acrylate (col.3, lines 35, 63-64; col.7, lines 17-20).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal patch comprising nicotine in a silicone matrix and having an adhesive layer on the skin facing surface as disclosed by US '947,

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and replace the adhesive layer by the acrylic adhesive layer disclosed in US '282, motivated by the teaching of US '282 that the disclosed acrylic pressure sensitive adhesive has the advantages of ease of manufacture, excellent safety history profile, high shear strength, low coast and chemical stability, with reasonable expectation of having a drug delivery device comprises nicotine and silicone matrix that is covered by acrylic adhesive skin contact layer that is safe and stable for treating drug dependency with success.

Allowable Subject Matter

7. Claims 3, 32, 33 and 36 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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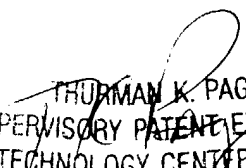
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615


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